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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,572	09/23/2002	B. Jack Longley		4237

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11/04/2004

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,572

Applicant(s)

LONGLEY, B. JACK

Examiner

Ralph Gitomer

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 13, 38, 43, 44, 53, 54, 61, 65, 72 and 89 is/are pending in the application.
- 4a) Of the above claim(s) 43, 44, 53, 54, 61, 65, 72 and 89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1651

Applicant's election without traverse of Group I, claims 1-9, 12, 13, 38, in the reply filed on 7/26/04 is acknowledged. The species of contact dermatitis is elected.

A proper abstract on a separate page must be submitted. It is difficult to determine the proper priority date for this application in view of the following rejection where this application does not provide enablement for the presently claimed invention. Priority is granted to 9/23/2002 at this time.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 12, 13, 38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-57 of copending Application No. 09/474,478. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '478 include the limitation of administering an antibody specifically in the currently pending independent claim 50 whereas the present claims are directed to administering any compound.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 12, 13, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Columbo in view of Mohammadi.

What has been searched and considered here is a method of preventing or treating dermatitis by inhibiting the stem cell factor signaling pathway.

Columbo (J of Immunology) entitled "The Human Recombinant C-Kit Receptor Ligand, rhSCF, Induces Mediator release From Human Cutaneous Mast Cells and Enhances IgE Dependent Mediator Release From Both Skin Mast Cells and Peripheral Blood Basophils" teaches in the abstract, a ligand for the C-Kit Proto oncogene receptor, a member of the tyrosine kinase receptor class, and the effects of C-Kit receptor ligand stem cell factor on the release of inflammatory mediators from human skin mast cells. There were effects on mast cells related to human allergic reactions and SCF may modulate mast cell function under physiologic conditions. On page 604 column 1, antibodies which recognize human C-Kit receptor is shown. On page 606

column 2 last paragraph bridging to page 607, the antibodies against C-Kit receptor and their effects were discussed.

The claims differ from Columbo in that they are directed to preventing or treating specifically where Columbo is measuring effects by the same method as claimed.

Mohammadi (Science) entitled "Structures of the Tyrosine Kinase Domain of Fibroblast Growth Factor Receptor in Complex with Inhibitors" teaches on page 955, protein tyrosine kinases are critical components of signaling pathways and selecting inhibitors have considerable therapeutic value.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to specifically treat with inhibitors as taught by Mohammadi in the method of Columbo because the inflammatory effects related to C-Kit and that such effects are modifiable are taught by Columbo. Mohammadi is directed to inhibiting the same pathways as Columbo for therapeutic reasons. The connection between C-Kit and cutaneous inflammation is clearly shown by Columbo. To select a known antibody such as ACK2 in view of Columbo who selects other antibodies would have been obvious because it would have the expected result. It is known in this art to treat disorders by administering antibodies to compounds associated with signaling pathways.

Art Unit: 1651

Claims 1-9, 12, 13, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The present claims are directed to preventing or treating contact dermatitis by administering a compound capable of inhibiting the stem cell factor signaling pathway as elected. Other claimed but not elected inventions include preventing or treating hyperpigmentation, asthma, cutaneous inflammation, anaphylaxis, mastocytosis, urticaria, hypersensitivity reactions, airway inflammation, interstitial cystitis, tumors, and contraception. The difficulty in performing the claimed functions, particularly preventing these conditions, is well known in this art.

The specification teaches on page 26, an animal model for skin inflammation was treated with anti-human SCF monoclonal antibodies where blocking SCF by administering ACL2 decreased inflammation in transgenic mice. On page 31 lines 8-10, "The fact that SCF transgenic mice have greater responses to allergic and irritant contactants shows that epidermal SCF can actively contribute to eczematous dermatitis." It is noted herein that there are significant differences between murine models and humans.

To then suggest that any compound that inhibits the stem cell factor signaling pathway to any degree with any selectivity will effectively prevent and treat all of the claimed disorders would not be likely without performing undue experimentation to

Art Unit: 1651

determine what compounds would be effective. For example, concentrated nitric acid would likely inhibit the stem cell factor signaling pathway but would not likely be effective to either prevent or treat the claimed disorders. None of the present claims include what the compound may be.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12, 13, 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 "a compound capable of" is improper because compounds do not have capabilities. Further, to describe the compound upon which the method depends in only a functional fashion is indefinite. For example, it may be that steroids to some degree inhibit the stem cell factor signaling pathway but one would not know if administering steroids infringe the present claims. The effect must be positively recited as to what occurs. "The stem cell factor" lacks antecedent basis. In claim 8 there is inconsistency between hypersensitivity reactions and urticaria.

Art Unit: 1651

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Longley (US 2002/0123031 A1) is a related application, currently pending.

Longley (US 6,576,812 B1) is a related patent.

Coleman (J of Immunology) teaches altering step cell factor.

Longley (J of the American Acad of Dermatology) teaches administering stem cell factor induces mast cell hyperplasia.

Funasaka (Molecular Biology of the Cell) teaches c-Kit functions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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